ACUTE PYROGENICITY TEST IN RABBITS
ADMINISTERED TEST ARTICLE ELASTOMER SHELL

ABSTRACT

The test solution that was prepared by rinsing one ELASTOMER SHELL in 0.9% Sodium Chloride, was injected into an ear vein in each of three rabbits at a dose level of 10 ml/kg body weight. None of the three animals had a temperature rise above 0.6°C and the sum of the three individual animal temperature rises was not greater than 1.4°C. Based on the parameters of this study the test article ELASTOMER SHELL is considered to be pyrogen-free.

ACUTE PYROGENICITY TEST IN RABBITS
ADMINISTERED TEST ARTICLE GEL[redacted]

ABSTRACT

The test solution that was prepared by rinsing test article GEL [redacted] (amount equivalent to the volume of gel contained in one device) in 0.9% Sodium Chloride, was injected into an ear vein in each of three rabbits at a dose level of 10 ml/kg body weight. None of the three animals had a temperature rise above 0.6°C and the sum of the three individual animal temperature rises was not greater than 1.4°C. Based on the parameters of this study the test article GEL[redacted] is considered to be pyrogen-free.

ACUTE PYROGENICITY TEST IN RABBITS
ADMINISTERED TEST ARTICLE LEAF VALVE ASSEMBLY

ABSTRACT

The test solution that was prepared by rinsing one LEAF VALVE ASSEMBLY in 0.9% Sodium Chloride, was injected into an ear vein in each of three rabbits at a dose level of 10 ml/kg body weight. None of the three animals had a temperature rise above 0.6°C and the sum of the three individual animal temperature rises was not greater than 1.4°C. Based on the parameters of this study the test article LEAF VALVE ASSEMBLY is considered to be pyrogen-free.